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08/217,780      03/25/94      WOZNEY

18M2/0621

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EXAMINER

|          |              |
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| ART UNIT | PAPER NUMBER |
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1814

**DATE MAILED:**

06/21/95

**This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS**

☒ This application has been examined ☒ Responsive to communication filed on 4/10/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s),        days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. ☐ Notice of References Cited by Examiner, PTO-892. 2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.  
3. ☐ Notice of Art Cited by Applicant, PTO-1449. 4. ☐ Notice of Informal Patent Application, PTO-152.  
5. ☐ Information on How to Effect Drawing Changes, PTO-1474. 6. ☐ \_\_\_\_\_.

## Part II SUMMARY OF ACTION

1. ☒ Claims 29-41 are pending in the application.
- Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☒ Claims 1-28 have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 29-41 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other \_\_\_\_\_

### EXAMINER'S ACTION

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Claims 29-41 are pending in the instant application. Claims 1-28 have been cancelled.

The previous 35 U.S.C. 112, first and second paragraph, rejections have been withdrawn in light of applicants' arguments and amendments to the claims.

The previous double-patenting rejection over application serial no. 08/164,102 has been withdrawn because the copending application has been abandoned.

Claims 29-32, 37, 38, 40, and 41 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the disclosed nucleic acid sequences and nucleic acid molecules encoding the disclosed amino acid sequences. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 29 and 30 are drawn to nucleic acid molecules that hybridize with the sequence of SEQ ID NO. 1 or DNA encoding the amino acids of SEQ ID NO. 2, respectively. The claims encompass any molecule that may hybridize with these sequences and which displays the ability to cause formation of tendon/ligament-like tissue. The specification does not disclose other molecules that hybridize with the sequences depicted by SEQ ID NO. 1 or 2. The specification also fails to disclose specific hybridization conditions, nor does it incorporate such conditions by reference. Thus, one of skill in the art would not know what is intended by

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"stringent hybridization conditions". Because applicants have not defined the intended conditions and the claims encompass innumerable different molecules, it would require undue experimentation for one of skill in the art to isolate each of the molecules encompassed by the claims and to screen the proteins encoding by said molecules for the requisite activity. Claims 29-32, 37, 38, 40, and 41 are deemed to be beyond the scope of the enabling disclosure.

Claims 33-36 and 39 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the disclosed nucleic acid molecules. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claim 33(b) is drawn to a DNA molecule that is a naturally occurring allelic sequence or equivalent degenerative codon sequence of the sequence depicted by SEQ ID NO. 1. The claims encompass any variant of the disclosed V1-1 gene that encodes a protein with the requisite ability to induce tendon/ligament formation. The specification does not disclose variants of the V1-1 gene. Due to the innumerable possible variant sequences included by the claims and the lack of guidance set forth by the specification regarding other possible variants, it would require undue experimentation for one of skill in the art to isolate, identify, and screen for activity all of the possible sequences.

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encompassed by the claims. Claims 33-36 and 39 are thus deemed to be beyond the scope of the enabling disclosure.

Claims 29-32, 37, 38, 40, and 41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 30 state that the claimed nucleic acid sequences encode proteins that "exhibit the ability to form tendon/ligament-like tissue". Claims 29 and 30 are indefinite in their recitation of "ability to form". The disclosed proteins do not form tissue, but induce formation of tendon/ligament-like tissue. Amending the claims to recite that the proteins have the ability to induce formation of such tissues would be remedial. Claims depending from claims 29 and 30 are also deemed to be indefinite.

Claim 30, part (b) is indefinite because it is drawn to sequences that hybridize with the molecules of parts (a) and (b). In other words, part (b) is drawn to molecules that hybridize to themselves.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 29-41 are rejected under 35 U.S.C. § 102(a) as being anticipated by Neidhardt et al. (WO 93/16099), for reasons of record.

Neidhardt et al. describe the human MP52 protein that is related to the TGF-beta family of proteins. The reference also describes the DNA sequence of MP52 and expression thereof using recombinant means. The protein of Neidhardt et al. and the DNA sequence encoding are 80% homologous to applicants' V1-1 protein. The instant claims are written so broadly as to encompass the MP52 protein of Neidhardt et al. and are anticipated by the reference.

Applicants traverse this rejection on the grounds that the sequences of the MP52 sequence and applicants' amino acid sequence (SEQ ID NO. 2) are distinct and thus there is no anticipation. The figures submitted by applicants and their arguments have been fully considered but are not deemed to be persuasive.

The sequences of applicants' V1-1 and MP52 share regions of homology such that the sequences would hybridize with each other. The claims encompass allelic variants (claim 33) and sequences that hybridize with the SEQ ID NO. 1 or the DNA encoding SEQ ID NO. 2 (claims 29 and 30). The claims thus include the sequences

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of Neidhardt et al., which could be considered to be an allelic variant or a hybridizing sequence. As discussed in the previous Office action, there is no showing that MP52 does not have the activity of the disclosed V1-1 protein. This rejection may be overcome by a showing that MP52 does not induce tendon or ligament formation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dian C. Jacobson whose telephone number is (703) 308-2973. The examiner can normally be reached Monday-Thursday 8:00 to 5:00. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216. The FAX number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Dian C. Jacobson*  
**DIAN C. JACOBSON**  
**PATENT EXAMINER**  
**GROUP 1800**